

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IBSA INSTITUT BIOCHIMIQUE SA et al.,

**Civil Action No. 23-54 (SRC)**

Plaintiffs,

## OPINION & ORDER

 $\mathbf{v}_i$ 

ACCORD HEALTHCARE, INC.,

Defendant.

**CHESLER, U.S.D.J.**

This matter comes before the Court on the application for claim construction by Plaintiffs IBSA Institut Biochimique SA, IBSA Pharma Inc., and Altergon SA (collectively, “IBSA”) and Defendant Accord Healthcare, Inc. (“Accord”). This case arises from patent infringement litigation involving four patents, but this Markman proceeding involves only one patent: U.S. Patent No. 11,241,382 (the “’382 patent.”) Plaintiff IBSA owns this patent and has sued the Defendant for patent infringement under the Hatch-Waxman Act. The parties seek claim construction of seven terms in the ’382 patent.

## ANALYSIS

## I. The law of claim construction

A court’s determination “of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). “[W]hen the district court reviews only evidence intrinsic to the

patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .

In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning

relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

## **II. Claim construction of the disputed terms**

- A. “a temporal distance of less than 30 minutes from the closest meal consumed by the patient”

In independent claim 1, the parties dispute the meaning of the claim term, “a temporal distance of less than 30 minutes from the closest meal consumed by the patient.” Plaintiff contends that the phrase has its plain and ordinary meaning, which is “a time of less than 30 minutes before or after the closest meal consumed by the patient.” Defendant contends that this phrase means, “within 30 minutes after the patient’s last meal.” Thus, the crux of the dispute is whether “temporal distance . . . from the closest meal” means “after the last meal” or “before or after the closest meal.”

Accord argues that the construction decision turns on the words, “consumed” and “from.” Accord contends that “consumed” is “past tense,” so the phrase refers only to the time period after the meal has been consumed. Accord’s characterization of “consumed” is inaccurate: although “consumed” is the past participle of the verb, “to consume,” in the phrase, “the closest meal consumed,” “consumed” is a participial adjective, not a verb. In “meal consumed by the patient,” “consumed” functions as an adjective which modifies the word, “meal.” The fact that it is possible to write other sentences in which “consumed” functions as a verb in the past tense is irrelevant, because it serves as an adjective in the claim term at issue. Accord contends that “the claim language is clear on its face,” but its grammatical analysis of that language is wrong. “Meal consumed” here means simply a consumed meal.

Accord also argues that the ordinary meaning of “from” supports its construction. The problem is that “from” is a preposition with multiple meanings in ordinary usage, and Accord has made no effort to explore the different meanings or differentiate them. Webster’s online dictionary offers four different meanings for “from.”<sup>1</sup> Indication of a starting point – the basis for Accord’s argument – relates to two of the four meanings. Accord offers no argument for why “temporal distance . . . from” should be construed as “time after.”<sup>2</sup>

Accord has offered no persuasive argument based on intrinsic evidence in support of its construction. IBSA argues that the meaning is “before or after the closest meal,” and that the specification clearly supports this:

The administration of the present solution of T4 thyroid hormone can be performed before or after the meal at issue; preferably it occurs before the meal. The term “consumed meal” is herein meant in the broad sense to indicate a meal which can be indifferently consumed before or after administration of the present solution of T4 thyroid hormone, within the above-mentioned temporal distances.

’382 patent, col.3 ll.18-25. The Court agrees with Plaintiffs: the specification makes crystal clear that Plaintiff’s proposed construction of this claim term is correct. Furthermore, as Plaintiffs point out, the quote above states that a preferred embodiment requires administration before a meal, and Accord’s proposed construction would exclude this preferred embodiment. “Such an interpretation is rarely, if ever, correct and would require highly persuasive evidentiary support.”

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<sup>1</sup> <https://www.merriam-webster.com/dictionary/from> (last accessed 11/19/2024.)

<sup>2</sup> The use of a distance metaphor to express the flow of time, “within a temporal distance,” leaves open the possibility that the administration may occur either *before* or *after* the consumed meal, as the specification explains. The use of the distance metaphor avoids ordinal implications. Defendant does not point out any wording that indicates a particular order of occurrence for the administration and meal. Compare to the language in dependent claim 3, “administered at a temporal distance . . . *before* said meal” (emphasis added.) In claim 3, the patentees specified an order of occurrence. Claim 1 does not do so.

Vitronics Corp. v. Conceptronic, 90 F.3d 1576, 1583 (Fed. Cir. 1996); see also Duncan Parking Techs., Inc. v. IPS Grp., Inc., 914 F.3d 1347, 1364 (Fed. Cir. 2019) (“a claim construction that excludes the preferred embodiment is highly disfavored.”)

Furthermore, the specification describes a few possible embodiments of the treatment method and then states:

In all above-mentioned forms, the reference time points for calculating the above-mentioned temporal distance are those when: (a) the oral dosage form is ingested, namely it contacted the mouth of the patient and (b) the closest meal has started.

’382 patent, col.4 ll.9-13. Again, this is crystal clear: the specification anchors “temporal distance” to two and only two points in time, with no limitation as to their order: 1) time of dosage ingestion; and 2) start time of closest meal. Nothing in this statement limits the concept of temporal distance to a particular order (either only before or only after the meal). In contrast, claim 3, which depends from claim 1, does limit its scope to administration of the dose before a meal. As Plaintiffs point out, if the Court adopted Defendant’s proposed construction, claim 3 becomes impossible. This alone is sufficient reason to reject Defendant’s proposed construction.

The Court adopts Plaintiffs’ proposed construction: “a temporal distance of less than 30 minutes from the closest meal consumed by the patient” means “a time of less than 30 minutes before or after the closest meal consumed by the patient.”

B. “Dosage unit” and “the form of a dosage unit”

Four dependent claims (7, 8, 15, and 16) refer to a solution “in the form of a dosage unit.” The parties have elected to present arguments about both the phrase “dosage unit” and “the form of a dosage unit,” although, in the claims, “dosage unit” never appears except within the phrase, “in the form of a dosage unit.” Thus the Court begins with the construction of “dosage unit.”

Plaintiffs propose that “dosage unit” means “unit of a pharmaceutical composition that contains a single dose or part of a dose.” Defendant proposes this construction: “single dose.” The crux of this dispute is the question of whether a dosage unit is limited to a single dose, or may also include a part of a dose.

As Plaintiffs observe, the key piece of intrinsic evidence is the only statement in the specification that contains the phrase, “dosage unit:”

Preferably, the present water-glycerol solutions are formulated and packaged as single **dosage units** (single-dose package); in this case, the suitable dose unit will typically contain from 5 to 1000 µg (or preferably from 10 to 500 µg) of T4 hormone.

’382 patent, col.4 ll.28-32. Plaintiffs argue that the use of the phrase, “single dosage units” is evidence that dosage units are not inherently single; were dosage units inherently single, “single dosage units” would be a redundant phrase, containing a superfluous duplication of the single attribute. “It is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous.” Intel Corp. v. Qualcomm Inc., 21 F.4th 801, 810 (Fed. Cir. 2021). The intrinsic evidence supports Plaintiffs’ proposed construction: a dosage unit is not limited to a single dose, but may contain either a single dose or a part of a single dose.<sup>3</sup>

As to “the form of a dosage unit,” Plaintiffs propose this construction: “the form of a unit of a pharmaceutical composition that contains a single dose or part of a dose.” Defendant

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<sup>3</sup> The Court finds that the intrinsic evidence clearly resolves the claim construction dispute over the meaning of “dosage unit.” “If the meaning of a claim term is clear from the intrinsic evidence, there is no reason to resort to extrinsic evidence.” Seabed Geosolutions (US) Inc. v. Magseis FF LLC, 8 F.4th 1285, 1287 (Fed. Cir. 2021). Still, the Court notes that the extrinsic evidence offered by Plaintiffs is consistent with and supports the Court’s construction. The United States Pharmacopeia defines “dosage unit” as “dosage forms containing a single dose or a part of a dose of drug substance in each unit.” (Lizza Dec. Ex. D at IBSATIR-SOL00113175.)

proposes this construction: “single dose container.” Because the Court has construed “dosage unit” as not limited to single units, Defendant’s proposed construction of the longer phrase must be rejected. “The form of a dosage unit” means “the form of a unit of a pharmaceutical composition that contains a single dose or part of a dose.”

C. “Single dose container”

Dependent claim 20 contains the phrase, “single dose container.” Plaintiffs propose that this means, “container that holds a single dose.” Defendant proposes this construction:

multicomponent laminated containers made of layers of polyethylene, ethylene vinyl alcohol copolymer resins, polyvinyl chloride, polyvinylidene chloride, polyvinyl acetate, fluorinated-chlorinated resins, ionomer resins, cyclic olefin copolymers, polyamide, polystyrene, polycarbonate, laminated metals, paper, obtaining containers with an ideal squeezing degree, so as to ensure complete discharge of the dose of solution by manual compression of the container, associated with an excellent protection of the solution

Defendant points out that this text has been copied from the patent specification, where it is preceded by this introduction: “An advantageous mode of packaging is represented by squeezable single-dose containers; in particular, as described in WO2018/073209, . . .” ’382 patent, col.5 ll.39-41. Thus, Defendant has taken a recommended example of single-dose packaging and proposed that “single dose container” be limited to that particular embodiment.

The Federal Circuit has — in its own words — “repeatedly warned” against limiting claims to particular embodiments: “although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.” Phillips, 415 F.3d at 1323. The Federal Circuit has explained:

The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language. Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim.

For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.

Superguide Corp. v. DirecTV Enters., 358 F.3d 870, 875 (Fed. Cir. 2004); see also Sumitomo

Dainippon Pharma Co. v. Emcure Pharms. Ltd., 887 F.3d 1153, 1158 (Fed. Cir. 2018)

(“Appellants’ claim construction arguments conflict with *Pfizer* and other precedent because they seek to import limitations from the specification into the claim.”) Moreover, the requirements for importing such a limitation are exacting: “Generally, a claim is not limited to the embodiments described in the specification unless the patentee has demonstrated a clear intention to limit the claim's scope with words or expressions of manifest exclusion or restriction.” i4i Ltd. P’ship v. Microsoft Corp., 598 F.3d 831, 843 (Fed. Cir. 2010) (quotation omitted). Defendant has not pointed to any expressions of manifest exclusion or restriction in the specification which could justify restricting claim 20 to a particular squeezable single dose container. In fact, Accord’s briefs completely overlook Federal Circuit law about importing limitations from specific embodiments.

Defendant has failed to persuade the Court that it has satisfied the requirements of Federal Circuit law for importing a claim limitation from a particular embodiment in the specification. The language of claim 20 has broader scope than the specification example of the squeezable single-dose container.<sup>4</sup> The Court agrees with Plaintiffs that “single dose container” has its ordinary meaning and that no construction is needed.

In conclusion, the Court construes the terms at issue as follows. “A temporal distance of less than 30 minutes from the closest meal consumed by the patient” means “a time of less than

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<sup>4</sup> For starters, Defendant has not even attempted to explain why the scope of “single dose container” should be restricted to a particular “squeezable” embodiment.



30 minutes before or after the closest meal consumed by the patient.” “The form of a dosage unit” means “the form of a unit of a pharmaceutical composition that contains a single dose or part of a dose.” “Single dose container” has its ordinary meaning and no construction of that term is needed.

**SO ORDERED.**

s/ Stanley R. Chesler  
STANLEY R. CHESLER, U.S.D.J.

Dated: November 20, 2024